

EXHIBIT M



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Pelvic Organ Prolapse

This Practice Bulletin was developed by the ACOG Committee on Practice Bulletins—Gynecology with the assistance of Scott W. Smilen, MD, and Anne M. Weber, MD, MS. The information is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

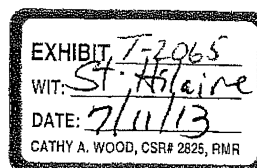


With the advancing age of the U.S. population, obstetrician-gynecologists are likely to encounter women with pelvic organ prolapse with greater frequency. The lifetime risk (to age 80 years) for undergoing surgery for prolapse or urinary incontinence has been estimated at 11% (1). Approximately 200,000 inpatient procedures for prolapse are performed annually in the United States (2). The most common indication for hysterectomy in women aged 55 years and older in the United States is prolapse (3). The purpose of this document is to review current treatment options.

Background

Pelvic organ prolapse occurs with descent of one or more pelvic structures: the uterine cervix or vaginal apex, anterior vagina (usually with bladder, cystocele), posterior vagina (usually with rectum, rectocele), or peritoneum of the cul-de-sac (usually with small intestine, enterocele). However, a specific definition of what constitutes clinically significant prolapse remains elusive. Although almost half of parous women can be identified as having prolapse by physical examination criteria, most are not clinically affected (4); the finding of prolapse on physical examination is not well correlated with specific pelvic symptoms.

Possible risk factors for pelvic organ prolapse include genetic predisposition, parity (particularly vaginal birth [5]), menopause, advancing age, prior pelvic surgery, connective tissue disorders, and factors associated with elevated intraabdominal pressure (eg, obesity, chronic constipation with excessive straining) (6, 7). Whether hysterectomy for conditions other than prolapse is a risk factor for subsequent prolapse is still controversial. Until recently, advocates of supracervical (or subtotal) hysterectomy claimed that preservation of the cervix (and, more important, the upper vagina and its pelvic attachments through the cardinal-uterosacral ligament complex) would prevent the development of subsequent prolapse. However, evidence from randomized trials comparing supracervical hysterectomy with total hysterectomy has shown no



difference in vaginal support with short-term follow-up after hysterectomy, regardless of cervical preservation or removal (8, 9).

Evaluation

Each woman's condition should be thoroughly evaluated to ascertain the nature and severity of her symptoms along with the extent of prolapse. Many patients with prolapse are asymptomatic and seek only reassurance or a better understanding of their condition. Women with asymptomatic or mildly symptomatic prolapse can be counseled that treatment is appropriate only when symptoms warrant it. It cannot be assumed that nonspecific symptoms, such as pelvic pressure or back pain, will be alleviated with prolapse treatment. The most specific symptom of prolapse is when the woman can see or feel a bulge of tissue that protrudes to or past the vaginal opening. Because prolapse is a dynamic condition responsive to the effects of gravity when women are in an erect position, some women may experience little or no bulging early in the day with progressively more protrusion as the day goes on, especially after long periods of physical exertion, such as lifting or standing.

Patients with prolapse, perhaps particularly anterior vaginal prolapse, may experience difficulty voiding or incomplete bladder emptying; however, symptoms of urinary urgency or frequency or urge incontinence are not related to prolapse severity. Women with advanced prolapse may recall symptoms of stress incontinence in the past that gradually improved and even resolved as the prolapse became worse. Some women with severe prolapse discover they can void more completely when the prolapse is reduced. Similarly, some women with posterior vaginal prolapse use manual pressure applied to the perineum or posterior vagina to assist defecation. Because many women will not volunteer such information, it is critically important that clinicians ask specific questions to assess voiding and defecating.

The maximum degree of descent may be observed on physical examination with the patient supine in heel stirrups, performing a Valsalva maneuver. If the patient suggests that her prolapse is not being seen at its worst extent, she can be asked to strain while in the standing position. Efficiency of bladder emptying should be evaluated by measuring the patient's voided volume when she has a comfortably full bladder, followed by assessment of postvoid residual urine volume by catheterization or bladder ultrasonography. Valsalva and cough stress testing can be performed with the prolapse reduced to determine if a subjectively stress-continent patient has occult (or potential) stress incontinence; however, cur-

rently, there is no consensus on how to best reduce prolapse for stress testing nor on how to use information from stress testing with and without prolapse reduction in making recommendations for care.

Several systems have been developed to classify pelvic organ prolapse. The Baden-Walker system (or some modification) is in widespread clinical use (see box, "Baden-Walker System for the Evaluation of Pelvic Organ Prolapse on Physical Examination"); the Pelvic Organ Prolapse Quantification (POP-Q) system (10) was introduced for use in clinical practice and research. Some have argued that the nine points of the POP-Q system may be more detailed than necessary for clinical practice, and the full POP-Q system may be better suited for clinical research purposes. The Baden-Walker system is probably adequate for clinical practice as long as descent or protrusion affecting all pelvic compartments (anterior, apical, and posterior) is assessed. It often is useful to include an estimation or measurement of the extent of protrusion relative to the hymen, as in the POP-Q system, to better assess change over time (see box, "Stages of Pelvic Organ Prolapse").

Clinical Considerations and Recommendations

► *Are effective nonsurgical treatments available for women with pelvic organ prolapse?*

The option of nonsurgical management should be discussed with all women with prolapse. Although pessary use is the only specific nonsurgical treatment, pelvic floor muscle rehabilitation and symptom-directed therapy may be offered, despite the lack of data supporting their use to prevent prolapse progression (11, 12).

Baden-Walker System for the Evaluation of Pelvic Organ Prolapse on Physical Examination

Grade posterior urethral descent, lowest part other sites

Grade 0: Normal position for each respective site

Grade 1: Descent halfway to the hymen

Grade 2: Descent to the hymen

Grade 3: Descent halfway past the hymen

Grade 4: Maximum possible descent for each site

Baden WF, Walker T. Fundamentals, symptoms and classification. In: Baden WF, Walker T, editors. *Surgical repair of vaginal defects*. Philadelphia (PA): I.B. Lippincott; 1992. p. 14.

Symptom-directed therapy with observation of prolapse (watchful waiting) can be recommended for women with low-stage prolapse (ie, stage I and stage II, especially when descent is still above the hymen) and nonspecific symptoms. The POP-Q stages of pelvic organ prolapse are shown in the box. Women with prolapse who are asymptomatic or mildly symptomatic can be observed at regular intervals, which can be conveniently combined with annual well-woman care unless new bothersome symptoms develop between visits. Although estrogen receptors are plentiful throughout the pelvis, their role in pelvic support is not fully understood, and there is no evidence currently to support the pharmacologic use of estrogen to prevent or treat prolapse.

Stages of Pelvic Organ Prolapse

Stages are based on the maximal extent of prolapse relative to the hymen, in one or more compartments.

Stage 0: No prolapse; anterior and posterior points are all -3 cm, and C (cervix) or D (posterior fornix) is between $-TVL$ (total vaginal length) and $-(TVL - 2)$ cm.

Stage I: The criteria for stage 0 are not met, and the most distal prolapse is more than 1 cm above the level of the hymen (less than -1 cm).

Stage II: The most distal prolapse is between 1 cm above and 1 cm below the hymen (at least one point is -1 , 0, or $+1$).

Stage III: The most distal prolapse is more than 1 cm below the hymen but no further than 2 cm less than TVL .

Stage IV: Represents complete procidentia or vault eversion; the most distal prolapse protrudes to at least $(TVL - 2)$ cm.

Pelvic Organ Prolapse Quantification System

Six vaginal sites used in staging prolapse:

Points Aa and Ba anteriorly

Points Ap and Bp posteriorly

Point C for the cervix or vaginal apex

Point D for the posterior fornix (not measured after hysterectomy)

Three additional measurements:

GH – genital hiatus

PB – perineal body

TVL – total vaginal length

Bump RC, Mattiasson A, Bo K, Brubaker LP, DeLancey JO, Klarskov P, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *Am J Obstet Gynecol* 1996;175:10–7.

Pessaries

Traditional indications for pessary treatment include pregnancy and specific medical contraindications to surgery in elderly and debilitated patients; however, pessaries also can be used in all circumstances when women prefer a nonsurgical alternative. Pessaries can be fitted in most women with prolapse, regardless of prolapse stage or site of predominant prolapse, and are used by 75% of urogynecologists as first-line therapy for prolapse (13). Pessary devices are available in various shapes and sizes, and can be categorized as supportive (such as a ring pessary) or space-occupying (such as a donut pessary). Pessaries commonly used for prolapse include ring pessaries (with and without support) and Gellhorn, donut, and cube pessaries.

In most patients (range, 50–73%), an appropriately sized pessary can be fitted successfully in one or two office visits; however, a lower percentage (range, 41–67%) maintain pessary use after fitting (14–19). Although some clinicians use pessaries less frequently for advanced prolapse, recent studies have not found an association between prolapse stage and the outcome of a pessary trial (16, 19). Other factors related to successful pessary fitting or continued pessary use are not consistent across studies (Tables 1 and 2). However, the type of pessary that can be fitted is probably related to the severity of prolapse. In one study protocol, ring pessaries were inserted first, followed by Gellhorn pessaries if the rings did not stay in place. Ring pessaries were used more successfully with stage II (100%) and stage III (71%) prolapse, and stage IV prolapse more frequently required Gellhorn pessaries (64%) (16). For women who can be fitted and whose pelvic organ support can be maintained with a pessary, treatment has a high likelihood of benefit. In one study, 2 months after successful fitting, 92% of patients were satisfied with pessary management, nearly all prolapse symptoms had resolved, and 50% of urinary problems were reduced (17). Neither stage of prolapse (19) nor sexual activity (18) contraindicates pessary use. Clinicians should discuss the option of pessary use with all women who have prolapse that warrants treatment based on symptoms. In particular, pessary use should be considered before surgical intervention in women with symptomatic prolapse.

Symptom-Directed Therapy

Therapy may include weight loss and exercise, in addition to therapy targeted at specific symptoms. Although weight loss and exercises (either aerobic exercise or pelvic floor muscle exercises) have not been proved beneficial specifically for prolapse treatment or prevention, such recommendations are appropriate as general health

Table 1. Factors Affecting Pessary Fitting for Pelvic Organ Prolapse

Author Percent of Study Population With Successful Pessary Fit	Factors Associated With Successful Pessary Fitting	Factors Not Associated With Successful Pessary Fitting
Clemons et al, 2004*: 73 of 100 women (73%)	Longer vaginal length (more than 7 cm) Narrower vaginal introitus (less than four finger-breadths)	Age Parity Estrogen use Sexually active Previous hysterectomy Previous prolapse surgery Pelvic organ prolapse stage Predominant prolapse compartment Genital hiatus size
Mutone et al, 2005†: 288 of 407 women (71%)	(not stated)	(not stated)

*Clemons JL, Aguilar VC, Tillinghast TA, Jackson ND, Myers DL. Risk factors associated with an unsuccessful pessary fitting trial in women with pelvic organ prolapse. *Am J Obstet Gynecol* 2004;190:345-50.

†Mutone MF, Terry C, Hale D, Benson JT. Factors which influence the short-term success of pessary management of pelvic organ prolapse. *Am J Obstet Gynecol* 2005;193:89-94.

Table 2. Factors Affecting Continued Pessary Use for Pelvic Organ Prolapse

Author Percent of Study Population With Continued Pessary Use	Factors Associated With Continued Pessary Use	Factors Not Associated With Continued Pessary Use
Brincat et al, 2004*: 82 of 136 women (60%)	Sexually active (vs not sexually active) Pessary use for prolapse (vs for stress incontinence)	Age Parity Menopausal status Surgical history
Mutone et al, 2005†: 168 of 407 women (41%)	No previous hysterectomy No previous surgery for prolapse Normal weight (vs obesity)	Age Levator ani strength Pelvic organ prolapse stage Predominant prolapse compartment Genital hiatus size Perineal body length Total vaginal length

*Brincat C, Kenton K, Fitzgerald MP, Brubaker L. Sexual activity predicts continued pessary use. *Am J Obstet Gynecol* 2004;191:198-200.

†Mutone MF, Terry C, Hale D, Benson JT. Factors which influence the short-term success of pessary management of pelvic organ prolapse. *Am J Obstet Gynecol* 2005;193:89-94.

guidelines. In addition, symptoms related to altered voiding or defecatory habits should be addressed. For example, patients with defecatory problems, such as incomplete emptying and straining, often benefit from behavior training (such as establishing a scheduled time to facilitate regular bowel habits), dietary modification (such as increased dietary fiber or fiber supplements as needed), and splinting or laxative or enema use to permit evacuation without straining. Women with urinary incontinence as their primary symptom can be treated with behavior modification (timed voiding), fluid intake alterations,

pelvic muscle training and exercise (see the following section), and medication as first steps.

Pelvic Floor Muscle Rehabilitation

Pelvic muscle training (Kegel exercises) is a simple, non-invasive intervention that may improve pelvic function. Whether Kegel exercises can resolve prolapse has not been studied since Kegel's original articles (20). Nevertheless, the benefit of pelvic floor muscle training has been clearly demonstrated for women with urinary or

fecal symptoms, especially incontinence. It is commonly recommended as adjunct therapy for women with prolapse and associated symptoms, often with symptom-directed therapy.

► *What are effective surgical treatments for uterine or vaginal vault prolapse?*

Hysterectomy is often the traditional surgical approach for women with uterine or uterovaginal prolapse. However, because the uterus plays only a passive role in prolapse, hysterectomy alone or hysterectomy with anterior or posterior colporrhaphy does not address the underlying problem of deficient apical support. When hysterectomy is performed for uterine prolapse, attention must be directed toward restoration of apical support once the uterus is removed. Surgical options for patients with apical prolapse (when hysterectomy has been performed remotely or as part of the current procedure) include abdominal sacral colpopexy and transvaginal suspension procedures using pelvic structures for fixation, such as the sacrospinous ligament(s), uterosacral ligaments, and iliococcygeus fascia or muscle.

Multiple case series on vaginal and abdominal approaches to apical prolapse have been summarized in extensive reviews (21, 22). These predominantly retrospective studies demonstrate a wide range of effectiveness for surgical treatment of prolapse at the vaginal apex, with failure rates ranging from 0% to 20% for each type of procedure (sacrospinous ligament fixation, uterosacral ligament suspension, endopelvic fascial suspension by vaginal approach, or abdominal sacral colpopexy by open or laparoscopic approach). Whether abdominal sacral colpopexy offers advantages in outcomes over vaginal approaches to prolapse repair is controversial.

A 2005 Cochrane review (6) of surgical management of prolapse concluded that, based on a synthesis of three randomized trials (23–25), compared with vaginal sacrospinous ligament fixation, abdominal sacral colpopexy has less apical failure and less postoperative dyspareunia and stress incontinence, but is also associated with more complications. The reported recurrence for vault prolapse was 3 in 84 abdominal sacral colpopexies versus 13 in 85 vaginal surgeries (relative risk [RR], 0.23; 95% confidence interval [CI], 0.07–0.77). However, operating time and patient recovery was longer with abdominal sacral colpopexy compared with vaginal sacrospinous ligament fixation. Short-term and long-term complications, particularly related to intraabdominal adhesions and small-bowel obstruction, may be more frequent after abdominal sacral colpopexy compared with vaginal prolapse repair. Therefore, clinicians should carefully consider each patient's risk for complications and potential for

recurrent prolapse, along with the patient's preferences, when making recommendations for abdominal sacral colpopexy or vaginal sacrospinous ligament fixation.

Whether results are superior with uterosacral versus sacrospinous ligament suspension is unknown; the two procedures have never been compared in a controlled or randomized trial. From case series of sacrospinous and uterosacral ligament vaginal suspensions, risks common to surgery in general are similar probably because the two procedures share the vaginal approach. However, some risks are specific to each procedure. Ureteral injury rates as high as 11% have been reported with uterosacral ligament suspension (26). Cystoscopy should be performed intraoperatively to assess for bladder or ureteral damage after all prolapse or incontinence procedures during which the bladder or ureters may be at risk of injury. If promptly identified and treated, such injury usually requires only suture release and replacement to avoid serious morbidity. However, ureteral injury occasionally requires reimplantation, particularly if recognition of the injury is delayed. Hemorrhage from pudendal vessels injured in sacrospinous ligament suspension is rare but can be life-threatening and is technically challenging to address. Buttock pain after sacrospinous suspension occurs infrequently and usually is self-limited but may require reoperation for suture removal to resolve persistent pain.

Outcomes of laparoscopic sacral colpopexy have been reported in case series (27–29) and one comparative cohort study (30). Recurrent apical prolapse occurred in only 4–7%, but anterior or posterior vaginal prolapse recurred in up to 32%. Without randomized trials, it is not possible to draw conclusions of similar efficacy compared with abdominal sacral colpopexy, but it does seem that for surgeons with advanced laparoscopic skills, sacral colpopexy can be accomplished, thereby avoiding laparotomy. However, even in the hands of experienced laparoscopists, a protracted learning curve is described for laparoscopic sacral colpopexy (28), and average operative times are almost an hour longer than for open sacral colpopexy (30), although postoperative recovery may be shorter.

Reviews of several case series of uterosacral ligament suspension describe recurrent prolapse in 4–18% of patients after relatively short follow-up (up to 4 years), although conclusions are limited by the inherent weaknesses of uncontrolled studies (26, 31–35). In one study of 168 women, 11 (6.5%) had recurrent prolapse at follow-up from 6 months to 3 years (34). In 72 of those women monitored for a mean of 5.1 years (range, 3.5–7.5 years), 11 (15.3%) experienced symptomatic recurrent prolapse of stage II or greater, although only two women (3%) had apical prolapse (36). Alternative sites for apical

support, such as sacrospinous ligament(s) or iliococcygeus fascia, can be used when the uterosacral ligaments are not easily accessible or are attenuated and unable to provide adequate support. Use of the iliococcygeus fascia during vaginal surgery has been reported in case series (37, 38).

► *What management options are recommended for women who are poor surgical candidates and who present with complete eversion of the vagina, with or without a uterus?*

In some cases, including women who are at such high risk of surgical or anesthetic complications that surgery is contraindicated, nonsurgical treatment will be first-line therapy. Expectant management, nonsurgical therapy, and surgery have not been directly compared for any patient population, including older or medically compromised women with advanced prolapse. In general, perioperative risk is increased in patients with concomitant medical problems. However, if surgery becomes necessary, limited data support its relative safety; morbidity occurs frequently but mortality is rare.

In 267 women aged 75 years or older, after primarily vaginal urogynecologic surgery, 26% had perioperative complications, most commonly blood loss, pulmonary edema, and congestive heart failure (39). In a study reviewing an administrative database of inpatient urogynecologic procedures in 264,340 women (40), mortality was increased in a nonlinear pattern with each decade of life: 1 in 10,000 for women younger than 60 years; 5 in 10,000 for women aged 60–69 years; 9 in 10,000 for those aged 70–79 years; and 28 per 10,000 for women aged 80 years and older. Complications were more frequent in women aged 80 years and older and in women who had reconstructive rather than obliterative surgery.

Colpocleisis (or colpectomy) can be offered to women who are at high risk for complications with reconstructive procedures and who do not desire vaginal intercourse. In a recent review, colpocleisis was reported as successful for prolapse repair in close to 100% of patients in modern retrospective series (41). However, the rate of reoperation for stress incontinence or recurrent prolapse after colpocleisis is unknown. Although complications are relatively common in this group of predominantly older patients, serious morbidity or mortality is uncommon. Concomitant hysterectomy is associated with increased blood loss, blood transfusion, and length of hospital stay, without known benefit. Few studies systematically assess pelvic symptoms, either before or after surgery. The Manchester procedure (amputation of the cervix combined with anterior and posterior colporrhaphy)

has been considered another option for older, frail women with prolapse, but it has been little used since the mid-1970s.

► *Are effective surgical treatments available for a woman with pelvic organ prolapse who prefers to avoid hysterectomy?*

For women who choose surgical management and who prefer uterine conservation (which may or may not include interest in further childbearing), the same procedures performed for vaginal suspension (after either remote or concomitant hysterectomy) can be performed without hysterectomy: uterosacral or sacrospinous ligament fixation by the vaginal approach, or sacral hysteropexy by the abdominal approach. Limited data on pregnancy outcomes (42, 43) and even fewer data on prolapse outcomes are available. Ideally, childbearing should be complete before considering surgery for prolapse to avoid the theoretical but plausible risk of recurrent prolapse after subsequent pregnancy and delivery. For women who become pregnant after prolapse repair, decisions regarding mode of delivery should be made on a case-by-case basis; evidence to guide such decisions is lacking.

Hysteropexy

In retrospective series review, prolapse recurrence ranges from 6.6% to 23.5% after sacral hysteropexy or sacral colpopexy (abdominal attachment of the lower uterus or upper vagina to the sacral promontory with synthetic mesh) (44, 45), and up to 30% for sacrospinous hysteropexy (43, 46). Complications include hemorrhage, hematoma, wound infection, small-bowel obstruction, incisional hernia, and mesh erosion. The laparoscopic approach has been used for hysteropexy, but data are limited (47, 48). Hysteropexy should not be performed by using the ventral abdominal wall for support because of the high risk for recurrent prolapse, particularly enterocele.

Round Ligament Suspension

Round ligament suspension is not effective in treating uterine or vaginal prolapse. A retrospective case series review on laparoscopic suspension to the round ligament found that 90% of patients had already experienced recurrent prolapse by 3 months postoperatively (49).

Colpocleisis

Some patients do not desire vaginal function for sexual activity or future childbearing and prefer to avoid hysterectomy. For these women, colpocleisis is an option.

► *Are effective surgical treatments available for a woman with anterior or posterior vaginal prolapse or both (ie, cystocele or rectocele or both)?*

Anterior vaginal prolapse (cystocele) may be repaired with traditional midline anterior colporrhaphy, with or without the addition of mesh or graft material, or by paravaginal repair, which can be accomplished vaginally or retropubically by open or laparoscopic access. No data are available on the effectiveness of laparoscopic paravaginal repair primarily for prolapse. Retrospective case series review regarding open retropubic and vaginal paravaginal repairs (in combination with other procedures for prolapse and often stress incontinence) show recurrent prolapse in 15–37% with relatively short follow-up up to 3 years (50–53). Controlled studies comparing open retropubic repair with vaginal paravaginal repair or studies comparing paravaginal repair by any approach with anterior colporrhaphy are lacking.

Posterior vaginal prolapse (rectocele) has traditionally been treated surgically by posterior colporrhaphy, with midline plication of the subepithelial vaginal tissue. Although in the past plication of the medial portion of the levator ani often was performed as an adjunct to posterior repair, its use has been largely abandoned because of postoperative dyspareunia except when postoperative sexual activity is not anticipated. Site-specific repair also can be accomplished, in which a specific “defect” in the vaginal muscularis or adventitia is visualized and repaired. Abdominal and laparoscopic approaches also have been suggested, usually in conjunction with sacral colpopexy, where mesh is placed along the posterior vagina, sometimes all the way to the perineal body (sacral colpoperineopexy).

No randomized trials compare posterior colporrhaphy with site-specific defect repairs; in one uncontrolled comparison (54), after site-specific repairs, prolapse recurred more frequently (33%) than after traditional midline plication (14%) within 1 year of follow-up. Dyspareunia remains a frequent and difficult postoperative problem, even when introital narrowing is avoided (55).

Colorectal surgeons have advocated the transanal approach to rectocele repair, with plication of redundant rectal mucosa and anterior rectal muscle. However, in a trial comparing transanal and transvaginal approaches (6, 56), transvaginal repair was more effective for subjective symptom relief and objective recurrence of posterior vaginal prolapse (rectocele and enterocele). The vaginal approach was associated with a smaller mean rectocele depth determined by defecography, and postoperative enterocele was less common, compared with

the transanal approach (6). Therefore, transvaginal posterior colporrhaphy is recommended over transanal repair for posterior vaginal prolapse.

► *What can be recommended regarding currently available graft materials for use in prolapse surgery?*

Biologic and synthetic graft materials have been used to augment traditional prolapse repairs, such as anterior and posterior colporrhaphy, as a substitute or reinforcement for the original vaginal tissue. For apical prolapse, new techniques use materials mounted on trocars to bypass native supportive structures (eg, uterosacral–cardinal ligament complex) in order to provide vaginal support. Despite the lack of risk–benefit information, many new techniques and products are being incorporated rapidly into clinical practice, even while continuous modifications are taking place in an attempt to reduce complications, particularly those related to mesh erosion, contraction (resulting in vaginal shortening and narrowing), and fistula. Given the pace of change with new techniques and products, any publication attempting to provide a comprehensive list will be outdated even before publication. Clinicians should follow the emerging literature closely to remain knowledgeable about which techniques and products should be avoided and which are ultimately proved to be of benefit to patients. The topic of graft materials is well covered in a review by Silva and Karram (57).

Although synthetic mesh used in early reports of abdominal sacral colpopexy was associated with good prolapse outcomes, mesh erosion occurred in some cases. Most cases of mesh erosion can be managed successfully with limited vaginal excision, incurring minimal morbidity; however, in rare cases, the entire mesh must be removed via laparotomy, often in the setting of refractory peritoneal infection, severe adhesions, and high likelihood of bowel complications. In an effort to reduce the risk of mesh erosion, some surgeons switched from synthetic mesh to allograft (cadaveric) fascia for abdominal sacral colpopexy. However, high rates of prolapse recurrence after abdominal sacral colpopexy using cadaveric fascia were initially reported in case series review (58–60), followed by randomized trial evidence (61). The use of cadaveric fascia for abdominal sacral colpopexy should be abandoned.

When choosing the best material for specific procedures, it is critically important that surgeons understand how certain characteristics of materials play a key role in the risk–benefit ratio for various types of surgery. Pore size in surgical mesh is one of the most important factors

in determining risk of postoperative infection. In addition, chemical coatings of materials can markedly influence the risk of complications. For example, silicone-coated synthetic mesh was used in sacral colpopexy with an unacceptably high rate of erosion, 24% (62), even after high erosion rates were reported in slings of similar material (63). It should be noted that some synthetic materials when used in abdominal surgery, such as abdominal sacral colpopexy, have a low rate of complications such as erosion, compared with their use in vaginal surgery, where the complication rate may be higher.

Following the success of the new generation of midurethral slings (in which synthetic material, mounted on trocars, was put in place through tiny incisions with minimal dissection), several new products have been introduced to augment or replace traditional prolapse procedures. Analogous to abdominal sacral colpopexy in which synthetic material is used to bypass native supports, products designed for use in treating apical prolapse are intended to replace deficient apical support with synthetic or biologic material.

In 2001, investigators reported 75 cases of infracoccygeal sacropexy (also known as posterior intravaginal slingplasty), a technique that initially used nylon mesh inserted via the ischioanal fossa into the posterior vaginal fornices, to treat vaginal vault prolapse (64). Despite encouraging initial results reported by the inventor, subsequent case series review has shown high rates of recurrent prolapse (65) and mesh complications (66) even after the material was changed to polypropylene.

Other devices for the placement of mesh to provide apical support have been developed and are currently being marketed in the United States. Long-term data are insufficient to make recommendations concerning these products.

Other products have been introduced for use with repair of anterior and posterior vaginal prolapse. Biologic graft material (xenograft or allograft) or synthetic material (absorbable or permanent) can be used in place of or in addition to traditional colporrhaphy (67). However, as with apical support materials, data are insufficient to determine risks or benefits. In one study of 312 patients undergoing vaginal surgery for prolapse repair, 98 (31.4%) with graft use did not have better prolapse outcomes than those without graft use, but complications (such as vaginal or graft infection) occurred much more frequently (68). A high rate of early failures has been reported after vaginal prolapse repair with porcine xenograft (69, 70). Although several studies have evaluated anterior colporrhaphy with and without mesh or graft materials of different types (71–79),

because of heterogeneity of material studied, small sample sizes, and short-term follow-up, it is not possible to draw definitive conclusions about the risk versus the benefit of absorbable or permanent synthetic materials in anterior colporrhaphy.

Given the limited data and frequent changes in the marketed products (particularly with regard to type of mesh material itself, which is most closely associated with several of the postoperative risks, especially mesh erosion), the procedures should be considered experimental and patients should consent to surgery with that understanding.

► *Can the occurrence of stress urinary incontinence after surgery for pelvic organ prolapse be anticipated and avoided?*

Many women with advanced prolapse, particularly prolapse involving the anterior vagina, will not have symptoms of stress urinary incontinence, either because the urethral sphincteric mechanism is in fact competent or because the advanced prolapse kinks the urethra, causing obstruction. Some of these stress-continent women will become stress incontinent after prolapse surgery. Subjectively stress-continent women with positive reduction stress test results (prolapse reduced) more frequently have stress urinary incontinence after prolapse repair if no antiincontinence procedure is performed; in small case series review, this ranges widely, from 8% to 60%. Until recently, clinicians were faced with a dilemma in trying to balance potential risks of an antiincontinence procedure without strong evidence of benefit. However, randomized trial evidence is now available to guide management decisions for apparently stress-continent women with prolapse.

In two randomized trials of women undergoing prolapse repair, postoperative stress incontinence was reduced significantly by the inclusion of an antiincontinence procedure. Improvement in stress incontinence was obtained without a concomitant worsening of voiding symptoms or impaired bladder emptying. In one trial of 50 women with a positive stress test result with prolapse reduction, tension-free vaginal tape (TVT) or suburethral plication was added to vaginal prolapse repair (80). With median follow-up of approximately 2 years, the TVT group had less stress incontinence, both subjectively (96% versus 64%) and objectively (92% versus 56%). For women with positive prolapse reduction stress test results who are planning vaginal prolapse repair, the TVT midurethral sling (rather than suburethral fascial plication) appears to offer better prevention from postoperative stress incontinence.

In the second trial, the Colpopexy and Urinary Reduction Efforts (CARE) trial, 322 women were randomly assigned to undergo either the Burch procedure or no antiincontinence procedure at the time of abdominal sacral colpopexy (81). Three months after surgery, fewer women in the Burch group (23.8%) had stress incontinence than in the no-Burch group (44.1%). In addition, among women with stress incontinence after surgery, fewer women in the Burch group were bothered (6.1%) by their symptoms, compared with 24.5% of women in the no-Burch group.

Although long-term data are not yet available, it seems evident that subjectively stress-continent women with positive stress test results (with prolapse reduced) benefit from the addition of an antiincontinence procedure at the time of prolapse repair. In making recommendations to women planning prolapse repair, clinicians should discuss the potential risks and benefits of adding an antiincontinence procedure, keeping in mind that prophylaxis against postoperative stress incontinence is not perfectly effective (just as antiincontinence procedures used for treatment are not perfectly effective). Even when antiincontinence procedures are performed, some women continue to have incontinence symptoms (both stress and urge) after surgery. Further study is needed to determine how to better prevent incontinence symptoms after prolapse repair, and whether more selective application of antiincontinence procedures will improve the risk-benefit ratio.

Women with negative stress test results despite prolapse reduction also may benefit from the addition of an antiincontinence procedure at the time of prolapse repair. In the CARE trial, women with negative stress test results (prolapse reduced) benefited from the addition of Burch colposuspension (20.8% with stress incontinence 3 months after surgery in the Burch group, compared with 38.2% in the no-Burch group). However, a smaller trial of women undergoing vaginal prolapse repair did not show a benefit from the addition of pubourethral ligament plication (82). Including only women with negative stress test results (prolapse reduced), 102 patients were randomly assigned to receive vaginal prolapse repair with or without pubourethral ligament plication. After 1 year, the proportion of women with stress incontinence was the same in both groups (8%). Until further data become available, clinicians should discuss with women the potential advantages and disadvantages of adding an antiincontinence procedure to prolapse repair when results of preoperative prolapse reduction stress testing are negative.

Summary of Recommendations and Conclusions

The following recommendations and conclusions are based on good and consistent scientific evidence (Level A):

- ▶ The only symptom specific to prolapse is the awareness of a vaginal bulge or protrusion. For all other pelvic symptoms, resolution with prolapse treatment cannot be assumed.
- ▶ Pessaries can be fitted in most women with prolapse, regardless of prolapse stage or site of predominant prolapse.
- ▶ Cadaveric fascia should not be used as graft material for abdominal sacral colpopexy because of a substantially higher risk of recurrent prolapse than with synthetic mesh.
- ▶ Stress-continent women with positive stress test results (prolapse reduced) are at higher risk for developing postoperative stress incontinence after prolapse repair alone compared with women with negative stress test results (prolapse reduced).
- ▶ For stress-continent women planning abdominal sacral colpopexy, regardless of the results of preoperative stress testing, the addition of the Burch procedure substantially reduces the likelihood of postoperative stress incontinence without increasing urgency symptoms or obstructed voiding.
- ▶ For women with positive prolapse reduction stress test results who are planning vaginal prolapse repair, TVT midurethral sling (rather than suburethral fascial plication) appears to offer better prevention from postoperative stress incontinence.

The following recommendations and conclusions are based on limited or inconsistent scientific evidence (Level B):

- ▶ Clinicians should discuss the option of pessary use with all women who have prolapse that warrants treatment based on symptoms. In particular, pessary use should be considered before surgical intervention in women with symptomatic prolapse.
- ▶ Alternative operations for uterine preservation in women with prolapse include uterosacral or sacrospinous ligament fixation by the vaginal approach, or sacral hysteropexy by the abdominal approach.

- ▶ Hysteropexy should not be performed by using the ventral abdominal wall for support because of the high risk for recurrent prolapse, particularly enterocele.
- ▶ Round ligament suspension is not effective in treating uterine or vaginal prolapse.
- ▶ Compared with vaginal sacrospinous ligament fixation, abdominal sacral colpopexy has less apical failure and less postoperative dyspareunia and stress incontinence, but is also associated with more complications.
- ▶ Transvaginal posterior colporrhaphy is recommended over transanal repair for posterior vaginal prolapse.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- ▶ Clinicians should discuss with women the potential risks and benefits in performing a prophylactic anti-incontinence procedure at the time of prolapse repair.
- ▶ Women with prolapse who are asymptomatic or mildly symptomatic can be observed at regular intervals, unless new bothersome symptoms develop.
- ▶ For women who are at high risk for complications with reconstructive procedures and who no longer desire vaginal intercourse, colpocleisis can be offered.
- ▶ Cystoscopy should be performed intraoperatively to assess for bladder or ureteral damage after all prolapse or incontinence procedures during which the bladder or ureters may be at risk of injury.

Proposed Performance Measure

The percentage of women with diagnosed symptomatic pelvic organ prolapse who are offered pessary use as first-line treatment

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The MEDLINE database, the Cochrane Library, and ACOG's own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and August 2006. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician-gynecologists were used.

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A—Recommendations are based on good and consistent scientific evidence.

Level B—Recommendations are based on limited or inconsistent scientific evidence.

Level C—Recommendations are based primarily on consensus and expert opinion.

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